UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

GABRIELA GARCIA UTTER, *Plaintiff*, vs. COLOPLAST CORP. AND COLOPLAST MANUFACTURING US, LLC., *Defendants.*	§	CASE NO.: _____ **COMPLAINT AND JURY TRIAL DEMAND**

COMPLAINT

Plaintiff GABRIELA GARCIA UTTER ("Plaintiff") files this Complaint against Defendants, COLOPLAST CORP. and COLOPLAST MANUFACTURING US, LLC ("Defendants"), and alleges as follows:

INTRODUCTION

1. On November 30, 2017, Plaintiff, GABRIELA GARCIA UTTER, was surgically implanted with an Altis Single Incision Sling System ("Altis"), a pelvic mesh product and medical device designed, manufactured, and marketed by Defendants, in order to treat the symptoms of stress urinary incontinence.

2. Defendants' Altis was intended to treat stress urinary incontinence and/or pelvic organ prolapse, however, neither Plaintiff nor her physicians were warned that the Altis was defective and negligently designed and manufactured. Plaintiff, as a result of being surgically implanted with Defendants' unreasonably dangerous and defective Pelvic Mesh Product, has

suffered, and continues to suffer, debilitating injuries, as described further herein. Plaintiff brings this suit for damages related to those injuries.

PARTIES

3. Plaintiff GABRIELA GARCIA UTTER is, and was at all times relevant to this action, a citizen and resident of Lindenhurst, Lake County, Illinois.

4. Defendant COLOPLAST CORPORATION ("Coloplast Corp.") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411.

5. Defendant COLOPLAST MANUFACTURING US, LLC ("Coloplast US") is a limited liability corporation organized and existing under Delaware law, maintaining its principal place of business at 1940 Commerce Drive, North Mankato, Minnesota 56002. Its registered office is 560 Park Street, #6, St. Paul, Minnesota 55103. Coloplast US is a wholly owned subsidiary of Coloplast Corp.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this civil action pursuant to 28 U.S.C. §1332(a), as the amount in controversy exceeds $75,000 and the Plaintiff is a citizen of a different state than one or more of the Defendants.

7. At all times material hereto, Defendants were engaged in the business of developing, manufacturing, designing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States, including the State of Illinois, either directly or indirectly, Pelvic Mesh Products intended to treat stress urinary incontinence and/or pelvic organ prolapse, including the Altis that was implanted into Plaintiff.

8. Venue in this district for pretrial proceedings in this civil action is proper under 28 U.S.C. §1391, as a substantial part of the events or omissions giving rise to this claim occurred in this district. Specifically, Plaintiff, a resident of Lake County, Illinois, was surgically implanted with the Altis at Evanston Hospital, 2650 Ridge Ave., Evanston, Cook County, Illinois 60201.

9. Defendants are subject to *in personam* jurisdiction in the U.S. District Court, Northern District of Illinois, Eastern Division, because Defendant's placed their defective Pelvic Mesh Products in the stream of commerce and all or some of those products were implanted into and caused personal injuries to Plaintiff, a resident of Lake County, Illinois, in the State of Illinois. Defendants have sufficient minimum contacts in Illinois or otherwise intentionally avails itself to the Illinois market through, without limitation, its advertisement, promotion, marketing, sales and/or distribution and other business activities, so as to render the exercise of jurisdiction over it by the U.S. District Court, Northern District of Illinois, Eastern Division, consistent with traditional notions of fair play and substantial justice.

DEFENDANTS' PELVIC MESH PRODUCTS

10. At all times material to this action, Defendants designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products, including the Altis, the product implanted into Plaintiff. These products were designed primarily for the purpose of treating stress urinary incontinence, as well as pelvic organ prolapse. These products were cleared, not approved, for sale in the United States after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this process does not require the applicant to prove safety or efficacy.

11. The products include those known as T-Sling-Universal Polypropylene Sling, Aris-Transobturator Sling System, Supris-Suprapubic Sling System**,** Novasilk-Synthetic Flat Mesh,

Exair-Prolapse Repair System, Restorelle, Smartmesh, Omnisure, and Minitape as well as any variations of these products and any unnamed Coloplast pelvic mesh product designed and sold for similar purposes, inclusive of the instruments and procedures for implementation. In addition, Coloplast manufactures, distributes, and sells products made of biologic materials known as Suspend-Tutoplast Processed Fascia Lata and Axis-Tutoplast Processed Dermis as well as any variations of these products and any unnamed Coloplast Pelvic Mesh Product designed and sold for similar purposes, inclusive of the instruments and procedures for Implementation.

12. These products are collectively referenced as Defendants' "Pelvic Mesh Products" or "Products."

FACTUAL BACKGROUND

13. At all relevant times, Defendants were in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, delivering, and introducing into interstate commerce, including, *inter alia,* within the United States and within the State of Illinois, either directly or indirectly through third parties, subsidiaries or related entities, pelvic mesh products, including the Altis, the pelvic mesh product at issue herein.

14. At all relevant times, the Altis was intended to be used, and for Plaintiff was used, to treat stress urinary incontinence.

15. Stress urinary incontinence is a type of incontinence characterized by leakage of urine during moments of physical stress, such as coughing, laughing, or sneezing.

16. Surgical mesh, including mesh used in the Pelvic Mesh Products, is a medical device that is generally used to repair weakened or damaged tissue. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic

organ prolapse or to support the urethra to treat stress urinary incontinence. Most pelvic mesh products are comprised of non-absorbable, synthetic, monofilament polypropylene mesh.

17. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material, as implanted in Plaintiff, is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, a chronic infectious response, and chronic pain. It also can cause new onset painful sexual relations, significant urinary dysfunction, vaginal shortening, and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh.

18. When these Pelvic Mesh Products are inserted into the female body, according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

19. In 1996, the FDA cleared the first pelvic mesh products for us in the treatment of stress urinary incontinence (SUI). These products included products manufactured, marketed, and distributed by Defendants. These products were cleared by the FDA under the abbreviated 510(k) clearance process. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was

ever conducted in regard to the pelvic mesh products, including the Pelvic Mesh Product at issue in this case.

20. On February 8, 2001, Mentor announced the purchase of Porges S.A. ("Porges"), a subsidiary of Sanofi-Synthelabo ("Sanofi"). At the time, Porges held the leading market share for urological products in France and held a strong position throughout Europe as one of the largest manufacturers of urological products, supplying a complete range of products including pelvic mesh products.

21. In May 2005, Mentor announced the U.S. launch of its new Aris™ Trans-Obturator Tape. According to Mentor's launch reports, "specifically designed to utilize Mentor's patented Trans-Obturator Technique (T.O.T.™), Aris represents the newest technical achievement and advanced generation of trans-obturator slings for the treatment of stress urinary incontinence in women." "The introduction of Aris furthers Mentor's position as a pioneer of the trans-obturator method for treating stress incontinence in women," commented Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation. "We are committed to driving innovation in the field of women's health to provide better solutions for physicians and the patients they serve."[1] FDA registration lists its proprietary device as "Mentor Aris Trans-Obturator Tape and Surgical Kit."

22. On October 12, 2005, ABISS and Mentor entered into a number of agreements pursuant to which ABISS licensed a number of ABISS' products to Mentor, which were thereafter marketed by Mentor under its trademarks, including its Aris trademark. On June 2, 2006, Mentor sold its surgical, urological, clinical and consumer healthcare business segments to Coloplast for

[1] Analytic Biosurgical Solutions ("ABISS").

$461,145,398, including inter alia, Mentor's October 12, 2005, agreements with ABISS and Mentor's Aris and Novasilk Pelvic Mesh Products.

23. At all times, the product marketed and sold in the United States as "Mentor Aris Trans-Obturator Tape and Surgical Kit" was manufactured by ABISS and, at all times after October 2, 2006, the product "Mentor Aris Trans-Obturator Tape and Surgical Kit" was exclusively marketed and sold in the United States by Coloplast Corp. from its principal place of business in Minneapolis, Minnesota.

24. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit."

25. On December 5, 2005, Mentor obtained 510(k) clearance for Mentor NovaSilk Mesh. Mentor NovaSilk Mesh is a permanent, synthetic knitted propylene mesh that is square in shape and is a sterile, single use device. The Mentor NovaSilk Mesh obtained 510(k) clearance based on substantial equivalence in material, function, performance, and design to the Gynemesh Prolene Soft (Polypropylene) Mesh cleared under 510(k) K013718 and knitted polypropylene already in use under Mentor's Aris Sling cleared under 510(k) K050148. Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation commented, "The addition of NovaSilk to Mentor's expanding portfolio of women's health products for pelvic organ prolapse or stress urinary incontinence reinforces the commitment of our urology franchise to surgeons and the patients they serve by providing high quality product offerings and customer service and support."

26. Coloplast A/S received 510(k) clearance for the Supris Retropubic Sling system 510(k) K111233 in June 2011, as a device substantially equivalent to the Mentor Aris Suprapubic Surgical Kit.

27. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with pelvic mesh products, such as the Pelvic Mesh Products manufactured, marketed, and distributed by Defendants. In this warning, the FDA indicated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare.**" (Emphasis in the original). The FDA had also received increased reports of complications associated with the pelvic mesh products used in both pelvic organ prolapse and stress urinary incontinence cases.

28. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (Emphasis in original).

29. The FDA Safety Communication further indicated that the benefits of using pelvic mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non mesh repair in all patients with POP and it may expose patients to greater risks."

30. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

31. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risks." (Emphasis in original).

32. The White Paper further stated that "these products are associated with serious adverse events ... Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair." In its White Paper, the FDA advises doctors to, *inter alia,* "[r]ecognize that in most cases POP can be treated successfully without mesh thus avoiding the risk of mesh related complications." The White Paper concludes by stating that the FDA "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

33. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of pelvic mesh products in pelvic repair procedures. In its Petition, Public Citizen warned that pelvic mesh products should be recalled because they offer no significant benefits but expose patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

34. In a December 2011, Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the transvaginal mesh inside the body as a serious complication associated with transvaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (constraction, retraction, or shrinkage) that result in

> taut sections of mesh…Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

35. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

36. As is known to the Defendants, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

37. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with Pelvic Mesh Products "indicate[] that serious complications can occur ... [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

38. After the 2011 FDA notification that mesh complications from POP repairs were "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patients should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted that "the women who received both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to their urinary symptoms."

39. In Defendants' 510(k) Summary (Kl21562) for the product at issue, Defendants state "the Altis Single Incision Sling System (herein after referred to as the Altis System) is substantially similar in performance, indications, design and materials to Coloplast' s Aris System (previously Mentor's) . . . . The American Medical System's MiniArc System and C.R. Bard Adjust Adjustable Single System Sling were also listed as substantially equivalent predicate devices. In the Device Description section, the Summary further states: "The sling material is manufactured using the commercialized Aris polypropylene mesh (K050148)." On information and belief, at all times relevant, the Altis System was manufactured by Diversified Plastics, Inc.

40. On November 5, 2012, Coloplast received 510(k) clearance of the Altis. According to the Coloplast U.S. website, the Altis sling material is the same as the Coloplast legacy products of Aris and Supris.[2]

41. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse ("cystocele") to stop selling and distributing their products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.[3]

42. Defendants did not, and have not, adequately studied the extent of the risks associated with their Pelvic Mesh Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

43. Defendants knew of should have known that their Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over

[2] www.coloplast.us/altis-en-us .aspx#section=product-desription_3.
[3] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants.

available feasible alternatives that do not involve the same risks. At the time Defendants began marketing the Altis, Defendants were aware that the Altis was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material, as implanted in Plaintiff, is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products, including the Altis, the product at issue herein. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

44. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

45. Defendants made the following statements regarding their products:

> (Aris has) Low rate of particle release from the sling – **minimizes increase in inflammatory response**. Atraumatic, smooth edges allow for easy passage during implantation. Macroporous design allows for optimal tissue integration. (Emphasis added).

46. Contrary to Defendants' assertions that its products minimize increase in inflammatory response:

A. In September 2009, results from a study were published in the BMC Women's Health relating to the comparison of host response and complications in patients implanted with Coloplast's Aris. Implants from the Aris group showed an **increase risk of erosion which was quantified at 4%**. Kaelin-Gambirasio, I, *Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up.*[4]

B. In September 2012, results from a study were published in the World Journal of Urology relating to the comparison of TVT vs TOT slings. 15 of 71 patients suffered adverse events including infection and erosion, **two thirds of which were implanted with the Aris**. Wadie BS, *TVT versus TOT, 2-year prospective randomized study*.[5]

47. Defendants made the following statements regarding their products:

> Novasilk is one of the lightest weight, thinnest meshes on the market, which translates into a more conforming mesh that may **reduce cases of inflammation, infection, or erosion** by having less implanted material.

48. Contrary to Defendants' assertions that its products are resistant to significant inflammation, infection, or erosion:

A. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia. [painful sexual intercourse]. Cosson, M., et al., *Mechanical properties of*

[4] BMC Womens Health. 2009 Sep 25; 9:28.
[5] World J Urol. 2012 Sep 26.

synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., *Tensile properties of commonly used prolapse meshes.* Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al., *Complications requiring reoperation following vaginal mesh kit procedures for prolapse.*[6]

B. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink *in vivo* leading to increased stiffness, pain and poor restoration of the normal properties of the vagina. Dora, C.D., et al., *Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, procine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery*. J Urol, 2004. 171(5): p. 1970-3.

C. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol.* 2002; 14:527-595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. *J Ural.* 2005; 65:1099-1103.

[6] AM J Obstet Gynecol, 2008. 199(6): p. 678 et-4.

D. In a study published in August 2012, Defendants' Novasilk was compared to other polypropylene on the market relating structural properties. Novasilk was found to have less porosity and increased stiffness than several of the other studied products supporting clinical observations among Plaintiffs' surgeons and the causative conclusion that properties of Defendants' mesh led to Plaintiffs' complications. Feola A, *Characterizing the ex vivo textile and structural properties of syntheticprolapse mesh products.* Int Urogynecol J. 2012 Aug 11.

49. Defendants' Pelvic Mesh Products, including the Altis product at issue and its predecessor products, were and are unreasonably susceptible to degradation and fragmentation inside the body; shrinkage or contraction inside the body; intense foreign body reaction; chronic inflammatory response; chronic wound healing; chronic infections in and around the mesh fibers; and nerve entrapment. Defendants knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks; to the extent they were known or knowable.

50. To this day, the Altis continues to be marketed to the medical community and to patients as safe, effective and reliable medical devices, implanted by safe, effective and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

51. Defendants omitted and downplayed the risks, dangers, defects, and disadvantages of their pelvic mesh products, including the Altis product at issue, and advertised, promoted, marketed, sold and distributed their pelvic mesh products, including the Altis, the product at issue,

as safe medical devices when Defendants knew or should have known that the products were not safe for their intended purposes, and that the products would cause, and did cause, serious medical problems, and in many patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the pelvic mesh products, including the Altis, were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

52. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, their products, including the Altis, the product at issue, have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

53. The specific nature of the Products' defects includes, but is not limited to, the following:

A. The use of polypropylene in the Pelvic Mesh Product and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries, but not limited to, painful recurrent erosions and associated intractable pain;

B. The design of the Altis to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced

chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

C. The use and design of arms and hooked anchors in the Altis sling, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region; and

D. The procedure to place the Altis sling requires blindly placing the arms the device through the thigh and obturator fossa that can injure major nerves that contribute to sexual function, mobility, and to bowel and bladder function.

FACT SPECIFIC ALLEGATIONS

54. On November 30, 2017, at Evanston Hospital, 2650 Ridge Ave., Evanston, Illinois 60201, Joby George, M.D. implanted Plaintiff GABRIELA GARCIA UTTER with a Coloplast Altis Single Incision Sling System (the "Device"), Lot No. 5567867, a medical device designed, manufactured, and marketed by Defendants, for the treatment of stress urinary incontinence. While the Device was intended to treat stress urinary incontinence, neither Plaintiff nor her physician were warned that the Device was defective and negligently designed and manufactured, as discussed further herein.

55. The Device implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendants' possession, and in the condition directed by and expected by Defendants.

56. Plaintiff's treating physician, Joby George, M.D., implanted the Device properly and appropriately.

57. On August 6, 2019, at Northwestern Medicine Lake Forest Hospital located in Lake Forest, Illinois, after suffering from severe pelvic pain and worsening stress urinary incontinence,

Christina E. Lewicky Gaupp, M.D. informed Plaintiff that the Device had eroded into her right anterior fornix and needed to be removed to avoid any further damage.

58. Neither Plaintiff nor her physician were warned that the Device was unreasonably dangerous, even when used exactly as intended by Defendants pursuant to Defendants' instructions for use. To the contrary, Defendants promoted, marketed, and sold their Pelvic Mesh Products, including the Device implanted in Plaintiff (and thousands of women like Plaintiff) to healthcare providers as a safe alternative to other procedures that did not incorporate the Defendants' Pelvic Mesh Products.

59. Had Defendants properly disclosed the risks associated with the Device implanted in Plaintiff for transvaginal use, Plaintiff would not have agreed to undergo treatment incorporating the Device. On information and belief, had Plaintiff's implanting physician, Joby George, M.D., been adequately and properly warned, she would have advised Plaintiff of the risks as part of her informed consent discussion and/or would have recommended a different treatment or no treatment at all.

60. As a direct and proximate result of having the Altis implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include any of the following: pudendal neuralgia, obturator neuralgia, pelvic floor tension myalgia, hip adductor myalgia, complex regional pain syndrome, erosion, recurrent urinary tract infections, interstitial cystitis, chronic dyspareunia, bowel and bladder dysfunction, and anorectal pain will likely undergo medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

61. The injuries suffered by Plaintiff were caused by the Defendants' wrongful acts, omissions, and fraudulent representations.

DISCOVERY RULE

62. Plaintiff could not have reasonably discovered the occasion, manner and/or means by which Defendants' breach of duty occurred until within two years of the filing of this complaint. Further, Plaintiff did not and could not have discovered through the exercise of reasonable diligence, including consultations with her physicians, the existence of her legal cause of action or the injuries caused by Defendants' breach of duty and/or defective products until within two years of the filing of this complaint. Defendants continue to deny that their Pelvic Mesh Products are defective and cause injuries, such as those suffered by Plaintiff, and continue to manufacture, market, and sell all or some of the Pelvic Mesh Products at issue. Any applicable statute of limitations has been tolled by the Defendants' knowledge, active concealment, and continued denial of material facts known by Defendants, who had a duty to disclose, and/or by the application of the discovery rule.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

63. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this complaint as is fully set forth herein and further alleges as follows:

64. At all times herein mentioned, Defendants were engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, using, supplying, selling, marketing, warranting, packaging, and advertising the Altis Single Incision Sling System (the "Device").

65. Defendants owed to Plaintiff and the public a duty to act reasonable and to exercise ordinary care in pursuit of the activities mentioned above. Defendants breached said duty of care.

66. At all times relevant hereto, Defendants owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation for use, issuance of warnings with respect to use, promotion, advertising, sale, and safety monitoring of the Device, and to adequately test and warn of the risk and dangers of the Device, both before and after sale.

67. Additionally, Defendants owed to Plaintiff and the public a duty to provide accurate, reliable, complete, and truthful information regarding the safety and dangerous propensities of the Device manufactured, used, distributed, and/or supplied by them, as well as to provide accurate, reliable, complete, and truthful information regarding the failure of the Device to perform as intended or as an ordinary consumer would expect.

68. At all times relevant hereto, Defendants breached the aforementioned duties in that Defendants negligently and carelessly manufactured, fabricated, designed, licensed, produced, compounded, assembled, inspected or failed to inspect, tested or failed to test, warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted, and advertised the Device in that said Device caused, directly and proximately, the injuries to Plaintiff through the failure of the Device to perform as intended or as an ordinary consumer would expect. Specifically, Defendants violated the duties of ordinary care and skill owed to Plaintiff in the following respects:

A. Failing to conduct adequate and appropriate testing of their Pelvic Mesh Products, including the Device at issue, to ensure they were safe for implantation in the female pelvis;

B. Placing their Pelvic Mesh Products, such as the Device at issue, on the market without first conducting adequate testing to determine possible side effects;

C. Placing their Pelvic Mesh Products, including the Device at issue, on the market without adequate testing of its dangers to humans;

D. Failing to recognize the significance of the medical literature, their own testing, and/or the testing of, and information regarding pelvic mesh products such as the Device at issue, when said literature/testing evidenced such products' potential harm to humans;

E. Failing to appropriately and promptly respond to the medical literature, their own testing, and/or the testing of, and information regarding pelvic mesh products such as the Device at issue, when said literature/testing evidenced such products' potential harm to humans;

F. Failing to promptly and adequately warn of their Pelvic Mesh Products', such as the Device at issue, to be harmful to humans;

G. Failing to promptly, adequately, and appropriately recommend testing and monitoring of pelvic mesh product patients, including patients implanted with the Device at issue, in light of the knowledge that such products had the potential to be harmful to humans;

H. Failing to properly, appropriately, and adequately monitor the post-market performance of Defendants' Pelvic Mesh Products, including the Device at issue, as well as said products' effects on patients;

I. Concealing from the FDA, the National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that Defendants' Pelvic Mesh Products, including the Device at issue, could be harmful to humans;

J. Promoting, marketing, advertising, and/or selling their Pelvic Mesh Products, including the Device at issue, for use on patients given their knowledge and experience of their Pelvic Mesh Products' potential harmful effects;

K. Failing to withdraw their Pelvic Mesh Products, including the Device at issue, from the market, restrict their use, and/or adequately warn of such products' potential dangers given their knowledge of the potential for its harm to humans;

L. Failing to fulfill the standard of care required of a reasonable, prudent, urogynecological medical device manufacturer engaged in the design, manufacturer, and marketing of such products, including the Device at issue;

M. Placing and/or permitting the placement of their Pelvic Mesh Products, including the Device at issue, into stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of the dangerousness of said products;

N. Failing to disclose to the medical community in a timely and appropriate manner facts relative to the potential of Defendants' Pelvic Mesh Products, including the Device at issue, to be harmful to humans;

O. Failing to respond or react promptly and appropriately to reports of their Pelvic Mesh Products, including the Device at issue, causing harm to patients;

P. Disregarding the safety of users and consumers of the Device at issue, as well as their other Pelvic Mesh Products, including Plaintiff, by failing to adequately warn of said products' potential harm to humans;

Q. Disregarding the safety of users and consumers of the Device at issue, as well as their other Pelvic Mesh Products, including Plaintiff, and/or her physicians, under the circumstances by failing to withdraw said products from the market and/or restricting their usage;

R. Disregarding publicity, government and/or industry studies, information, documentation, recommendations, consumer complaints, and reports and/or other information regarding the hazards of pelvic mesh products and their potential harm to humans;

S. Failing to exercise reasonable care in informing physicians and/or hospitals using Defendants' Pelvic Mesh Products, including the Device at issue, about their knowledge regarding said products' potential harm to humans;

T. Failing to remove their Pelvic Mesh Products, including the Device at issue, from the stream of commerce;

U. Failing to test their Pelvic Mesh Products, including the Device at issue, properly and/or adequately so as to determine their safety for use;

V. Promoting their Pelvic Mesh Products, including the Device at issue, as safe and/or safer than other comparative methods/products;

W. Promoting their Pelvic Mesh Products, including the Device at issue, on websites aimed at creating user and consumer demand;

X. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries resulting from their Pelvic Mesh Products, including the Device at issue;

Y. Failing to use due care under the circumstances; and

Z. Failing to monitor, analyze, and report to the FDA, medical community, their product users, and/or physicians and/or hospitals, adverse post-surgical outcomes stemming from the use of their Pelvic Mesh Products, including the Device at issue.

69. Defendants' acts constitute violations of the duty of care and skill owed by Defendants to Plaintiff.

70. Plaintiff used and was implanted with Defendants' Pelvic Mesh Product, the Altis Single Incision Sling System, that was reasonably foreseeable.

71. As the direct and proximate result of Defendants' negligent and/or reckless and/or wanton breaches of their aforementioned duties with respect to the Device, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, said Plaintiff prays for judgment against Defendants.

COUNT II: STRICT LIABILITY – DESIGN AND MARKETING

72. Additionally, or in the alternative, if same be necessary, Plaintiff realleges and incorporates by reference each of the foregoing paragraphs 1 through 68 of this Complaint as if fully set forth herein and further alleges as follows:

73. Defendants were and are engaged in the business of selling their Pelvic Mesh Products, including the Device aforementioned, in the State of Illinois.

74. The Device, manufactured, designed, marketed, promoted, and sold by Defendants, was expected to, and did, reach Plaintiff and her treating physician without substantial change in the condition in which it was sold. The Device was defective at the time of manufacture, development, design, production, testing, inspection, endorsement, prescription, sale, and distribution, and at the time it left the possession of the Defendants.

75. Defendants are manufacturers and/or suppliers of pelvic mesh products, specifically the Device at issue, and are strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling, and placing their Pelvic Mesh Products, specifically the Devise at issue, into the stream of commerce.

76. At the time Defendants' Pelvic Mesh Products, specifically the Devise at issue, left the possession of Defendants and entered the stream of commerce, the Device at issue was in an unreasonably dangerous and defective condition.

77. First, Defendants' Pelvic Mesh Product, the Device at issue, contained unreasonably dangerous design defects. Said defects include, but are not limited to:

A. The Device was not reasonably safe as intended to be used;

B. The Device had an inadequate design for the purposes of a pelvic mesh product intended to treat SUI;

C. The Device contained a defective design, which resulted in an unreasonably high probability of complications and/or injuries including but not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss,

neuropathic pain, and other acute and chronic nerve damage and pain, nerve damage, pelvic floor damage, and chronic pelvic pain,

D. The Device's defective design resulted in a pelvic mesh product which had risks which exceeded the benefits of the device;

E. The Device's defective design resulted in a pelvic mesh product which was more dangerous than the ordinary consumer would expect;

F. The Device's product failed to perform in a manner reasonably expected in light of its nature and intended function, and subjected Plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person; and

G. Defendants' Pelvic Mesh Products, specifically the Device at issue, were defective due to inadequate pre-market testing.

78. Defendants' Pelvic Mesh Products, specifically the Device at issue, were also defective due to inadequate warnings or instructions, including, but not limited to:

A. Failing to provide adequate warnings and/or instructions when Defendants knew, or should have known, that their Pelvic Mesh Products, specifically the Device at issue, created, among other things, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic pain, and other acute and chronic nerve damage and pain, nerve damage, pelvic floor damage, and chronic pelvic pain;

B. Failing to provide adequate initial warnings and post-marketing warnings or instructions after Defendants knew or should have known of the extreme risks associated with their Pelvic Mesh Products, including the Device at issue, and

continued to promote and sell those products in absence of those adequate warnings;

C. Insufficiently alerting Plaintiff and Plaintiff's treating physician about the dangers that the Device at issue posed to consumers, including the risk of adverse events or complications, subjecting Plaintiff to risks which exceeded the benefits of the Device at issue;

D. Containing misleading warnings emphasizing the safety and efficacy of the Device at issue, while downplaying the risks associated with it, thereby making use of the Device at issue more dangerous than the ordinary consumer would expect;

E. Containing insufficient and/or incorrect warnings to alert consumers, including Plaintiff, through her implanting physician, regarding risk, scope, duration, and severity of the adverse events and/or complications associated with the Device at issue;

F. Failing to disclose the fact that the Device at issue was inadequately tested;

G. Failing to convey adequate post-market warnings regarding the risk, severity, scope and/or duration of the dangers posed by the Device at issue; and

H. Failing to contain instructions sufficient to alert consumers to the dangers posed by the Device at issue.

79. Plaintiff used the Device at issue for its intended purpose.

80. Neither Plaintiff nor her implanting physician could have discovered any defect in the Device at issue through the exercise of due care.

81. Defendants, as designer, manufacturer, marketer, and distributor of pelvic mesh products, are held to the level of knowledge of an expert in their field.

82. Plaintiff and her implanting physician did not have substantially the same knowledge as Defendants – the designer, manufacturer, marketer, and distributor of the Device at issue.

83. As a direct and proximate result of one or more of these wrongful acts or omissions made by the Defendants, Plaintiff has suffered and continues to suffer devastating injuries and damages and continues to require medical treatment due to these injuries.

WHEREFORE, said Plaintiff prays for judgment against Defendants.

COUNT III: STRICT LIABILITY – NON-SPECIFIC DEFECT

84. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs 1 through 80 of this Complaint as if fully set forth herein and further alleges as follows:

85. Defendants had a duty to place into the stream of commerce, manufacture, distribute, market, promote, and sell the Altis Single Incision Sling System (the "Device") in a manner that was not defective and not unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed, and sold.

86. Defendants did in fact sell, distribute, supply and/or promote the Device to Plaintiff and her implanting physician.

87. Defendants expected that the Device it was selling, distributing, supplying, manufacturing, and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the State of Illinois, including Plaintiff and her implanting physician, without substantial change in its condition.

88. At the time the Device left the possession of Defendants and the time the Device entered the stream of commerce, the Device was in an unreasonably dangerous, unsafe, and defective condition. These defects include, but are not limited to, the following:

A. By posing an unreasonably high probability of complications and/or injuries to the user, the Device did not perform in a manner reasonably to be expected in light of its nature and intended function;

B. The Device failed to perform in a manner reasonably expected in light of its nature and intended function, and subjected Plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person; and

C. The Device otherwise possessed a condition which made it unreasonably dangerous for its intended and foreseeable use.

89. Plaintiff used the Device for its intended purpose.

90. Neither Plaintiff nor her implanting physician could have discovered any defect in the Device through the exercise of due care.

91. Defendants, as designer, manufacturer, marketer, and distributor of pelvic mesh products are held to the level of knowledge of an expert in their field.

92. Plaintiff and her implanting physician did not have substantially the same knowledge as Defendants – the designer, manufacturer, marketer, and distributor of the Device.

93. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff has suffered and continues to suffer devastating injuries and damages and continues to require medical treatment due to these injuries.

WHEREFORE, said Plaintiff prays for judgement against Defendants.

COUNT III: FRAUD

94. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs 1 through 93 of this Complaint as if fully set forth herein and further alleges as follows:

95. Under Illinois law, "the elements of common law fraud are: (1) [a] false statement of material fact; (2) known or believed to be false by the party making it; (3) intent to induce the other party to act; (4) action by the other party in [justifiable] reliance on the truth of the statement; and (5) damage to the other party resulting from such reliance."[7]

96. Defendants were and are engaged in the business of selling their Pelvic Mesh Products, including the Altis Single Incision Sling System (the "Device") aforementioned, in the State of Illinois.

97. The Device, manufactured, designed, marketed, promoted, and sold by Defendants, was expected to, and did, reach Plaintiff and her treating physician without substantial change in the condition in which it was sold. The Device was defective at the time of manufacture, development, design, production, testing, inspection, endorsement, prescription, sale, and distribution, and at the time it left the possession of the Defendants.

98. At the time Defendants' Pelvic Mesh Products, specifically the Devise at issue, left the possession of Defendants and entered the stream of commerce, the Device at issue was in an unreasonably dangerous and defective condition.

99. Defendants knew of should have known that their Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

[7] *Metro. Cap. Bank & Tr. v. Feiner*, 2020 IL App (1st) 190895, 38.

100. Defendants knew, or should have known, that their warnings were insufficient to fully put Plaintiff and Plaintiff's implanting physician on notice of the potential dangers and risks of the Device by failing to inform them of the following material facts:

A. Defendants' Pelvic Mesh Products, specifically the Device at issue, created, among other things, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic pain, and other acute and chronic nerve damage and pain, nerve damage, pelvic floor damage, and chronic pelvic pain;

B. Defendants' Pelvic Mesh Products, specifically the Device at issue, was inadequately tested;

C. Defendants' Pelvic Mesh Products, specifically the Device at issue, could be harmful to humans;

D. Defendants' Pelvic Mesh Products, specifically the Device at issue, posed extreme risks of adverse events or complications; and

E. Defendants' Pelvic Mesh Products, specifically the Device at issue, subject consumers, such as Plaintiff, to risks which exceed the benefits of the Device.

101. Additionally, Defendants knew, or should have known, that their warnings were misleading and/or inaccurate due to the following:

A. Defendants failed to provide adequate initial warnings and post-marketing warnings or instructions after Defendants knew or should have known of the extreme risks associated with their Pelvic Mesh Products, including the Device at issue;

B. Defendants' warnings misled consumers by emphasizing the safety and efficacy of the Device at issue, while downplaying the risks associated with it, thereby making the use of the Device at issue more dangerous than the ordinary consumer would expect; and

C. Defendants' warnings contained insufficient and/or incorrect information to alert consumers, including Plaintiff, through her implanting physician, regarding the risk, scope, duration, and severity of the adverse events and/or complications associated with the Device at issue.

102. Defendants knew, or should have known, that their insufficient, misleading, and inaccurate warnings would induce consumers, including Plaintiff and her implanting physician, to rely on them when evaluating whether to use Defendants' Pelvic Mesh Products, including the Device at issue, as the appropriate course of treatment for stress urinary incontinence and/or pelvic organ prolapse.

103. Defendants, as designer, manufacturer, marketer, and distributor of pelvic mesh products, are held to the level of knowledge of an expert in their field.

104. Plaintiff and her implanting physician did not have substantially the same knowledge as Defendants – the designer, manufacturer, marketer, and distributor of the Device.

105. Neither Plaintiff nor her implanting physician could have discovered any defect in the Device through the exercise of due care.

106. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff has suffered and continues to suffer devastating injuries and damages and continues to require medical treatment due to these injuries.

WHEREFORE, said Plaintiff prays for judgement against Defendants.

COUNT IV: CONSUMER FRAUD ACT

107. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs 1 through 106 of this Complaint as if fully set forth herein and further alleges as follows:

108. Under the Illinois Consumer Fraud Act ("ICFA"), unfair or deceptive acts or practices such as "the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression, or omission of such material fact…in the conduct of any trade or commerce" are unlawful.[8]

109. Additionally, the ICFA allows plaintiffs to "allege that conduct is unfair…without alleging that the conduct is deceptive."[9]

110. The court in *Dolemba* evaluates the following factors in order to determine whether conduct is "unfair" under the ICFA: "(1) whether the practice offends public policy; (2) whether it is immoral, unethical, oppressive, or unscrupulous; [and] (3) whether it causes substantial injury to consumers."[10] The court offers further guidance on the evaluation and construction of the three aforementioned factors by stating that a "practice may be unfair because of the degree to which it meets one of the criteria or because to a lesser extent it meets all three."[11]

[8] "Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965,1 in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5(a) of the Federal Trade Commission Act." 815 Ill. Comp. Stat. Ann. 505/2.

[9] *Dolemba v. Illinois Farmers Ins. Co.,* 213 F. Supp. 3d 988, 997 (N.D. Ill. 2016).

[10] *Id.*

[11] *Id.*

111. The conduct of Defendants clearly caused "substantial injury to" Plaintiff, due to their failure to alert Plaintiff and her implanting physician of the adverse events associated with their Pelvic Mesh Products, including the Device at issue, which, Defendants knew, or should have known, would lead to "substantial injury" amongst women, including Plaintiff, that were implanted with Defendants' Pelvic Mesh Products, including the device at issue.

112. The adverse events known to Defendants in July of 2011 through the FDA's safety communication include, but are not limited to, the following:

A. Polypropylene mesh can cause chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh;

B. Erosion of mesh through the vagina is the most common and consistently reported mesh-related complication from transvaginal POP surgeries using mesh;

C. Mesh erosion can require multiple surgeries to repair and can be debilitating for women; and

D. Surgery or multiple surgeries may not resolve the complications caused by mesh erosion.

113. Defendants, despite their knowledge of the above risks and complications that their Pelvic Mesh Products, including the Device at issue, can cause, continued to promote their Pelvic

mesh Products, including the Device at issue, on websites aimed at creating user and consumer demand as safe and/or safer than other comparative products.

114. For the reasons aforementioned, Defendants participated in acts and practices that caused Plaintiff "substantial injury" to such a degree that the said aforementioned third factor in determining whether such acts and practices where unfair within the meaning of the ICFA has clearly been established by the above acts taken by Defendants.

115. Therefore, Defendants violated the ICFA, making them liable to Plaintiff for the substantial and debilitating injuries, symptoms and conditions suffered by Plaintiff due to Defendants violation of the ICFA.

WHEREFORE, said Plaintiff prays for judgment against Defendants.

PUNITIVE DAMAGES

116. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs 1 through 112 of this Complaint as if fully set forth herein and further alleges as follows:

117. At all times relevant herein, Defendants: (1) Knew that their pelvic mesh products, including the Device at issue, were dangerous, ineffective, and caused significant, life altering complications and side-effects; (2) Concealed the dangers and health risks from Plaintiff, physicians, hospitals, other medical providers, the FDA, its users and the public at large; (3) Made misrepresentations to Plaintiff, physicians, hospitals, other medical providers, its users and the public at large as to the safety and efficacy of their pelvic mesh products, including the Device at issue; and (4) with full knowledge of the health risks associated with their pelvic mesh products, including the Device at issue, and without adequate warnings of the same, manufactured, designed, marketed, promoted,

developed, sold and/or distributed their pelvic mesh products, including the Altis, for routine use.

118. Defendants, by and through their officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent, and oppressive conduct towards Plaintiff and the public, acted with willful, wanton, and/or reckless disregard for the safety of Plaintiff and the general public. As such, the conduct of Defendants warrants the imposition of punitive damages under all applicable legal standards.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands trial by jury, and prays for judgment against Defendants individually, jointly, and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. For past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;
2. For past and future economic and special damages, according to proof at the time of trial;
3. For past and future medical and incidental expenses, according to proof at the time of trial;
4. For past and future loss of earnings and impaired earning capacity, according to proof at the time of trial; and
5. For past and future mental and emotional distress, according to proof at the time of trial.
6. For punitive and exemplary damages in a reasonable amount determined to be fair and just by the jury;
7. For costs, attorneys' fees, interest, or any other relief, monetary or equitable, to which she is entitled; and
8. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues in the above-captioned matter.

Dated: August 6, 2021

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